HEALTH AND SAFETY CODE

TITLE 2. HEALTH

SUBTITLE B. HEALTH PROGRAMS

This Chapter 50, consisting of Secs. 50.0001 to 50.0007, was added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2.

See also another Chapter 50, consisting of Secs. 50.0001 to 50.0102, as added by Acts 2019, 86th Leg., R.S., Ch. 413 (S.B. 20), Sec. 5.01.

See also another Chapter 50, consisting of Secs. 50.001 to 50.007, as added by Acts 2019, 86th Leg., R.S., Ch. 889 (H.B. 3405), Sec. 1.

CHAPTER 50. CANCER CLINICAL TRIAL PARTICIPATION PROGRAM

Sec. 50.0001. DEFINITIONS. In this chapter:

(1) "Cancer clinical trial" means a research study that subjects an individual to a new cancer treatment, including a medication, chemotherapy, adult stem cell therapy, or other treatment.

(2) "Inducement" means the payment of money, including a lump-sum or salary payment, to an individual for the individual's participation in a cancer clinical trial.

(3) "Program" means the cancer clinical trial participation program established under this chapter.

(4) "Subject" means an individual who participates in the program.

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2, eff. September 1, 2019.

Sec. 50.0002. ESTABLISHMENT. An independent, third-party organization may develop and implement the cancer clinical trial participation program to provide reimbursement to subjects for ancillary costs associated with participation in a cancer clinical trial, including costs for:

(1) travel;

(2) lodging;

(3) parking and tolls; and

(4) other costs considered appropriate by the organization.

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2, eff. September 1, 2019.

Sec. 50.0003. REQUIREMENTS; NOTICE. (a) The program:

(1) must collaborate with physicians and health care providers to notify a prospective subject about the program when:

(A) the prospective subject provides informed consent for a cancer clinical trial; or

(B) funding is available to provide the program for the cancer clinical trial in which the prospective subject participates;

(2) must reimburse subjects based on financial need, which may include reimbursement to subjects whose income is at or below 700 percent of the federal poverty level;

(3) must provide reimbursement for ancillary costs, including costs described by Section 50.0002, to eliminate the financial barriers to enrollment in a clinical trial;

(4) may provide reimbursement for reasonable ancillary costs, including costs described by Section 50.0002, to one family member, friend, or other person who attends a cancer clinical trial to support a subject; and

(5) must comply with applicable federal and state laws.

(b) The independent, third-party organization administering the program shall provide written notice to prospective subjects of the requirements described by Subsection (a).

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2, eff. September 1, 2019.

Sec. 50.0004. REIMBURSEMENT REQUIREMENTS; NOTICE. (a) A reimbursement under the program must:

(1) be reviewed and approved by the institutional review board associated with the cancer clinical trial for which the reimbursement is provided; and

(2) comply with applicable federal and state laws.

(b) The independent, third-party organization operating the

program is not required to obtain approval from an institutional review board on the financial eligibility of a subject who is medically eligible for the program.

(c) The independent, third-party organization operating the program shall provide written notice to a subject on:

(1) the nature and availability of the ancillary financial support under the program; and

(2) the program's general guidelines on financial eligibility.

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2, eff. September 1, 2019.

Sec. 50.0005. REIMBURSEMENT STATUS AS INDUCEMENT. Reimbursement to a subject of ancillary costs under the program:

(1) does not constitute an inducement to participate in a cancer clinical trial;

(2) is not considered coercion or the exertion of undue influence to participate in a cancer clinical trial; and

(3) is meant to accomplish parity in access to cancer clinical trials and remove barriers to participation in cancer clinical trials for financially burdened subjects.

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2, eff. September 1, 2019.

Sec. 50.0006. FUNDING. The independent, third-party organization that administers the program may accept gifts, grants, and donations from any public or private source to implement this chapter.

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2, eff. September 1, 2019.

Sec. 50.0007. COLLABORATION. The independent, third-party organization that administers the program may collaborate with the Cancer Prevention and Research Institute of Texas established under Chapter 102 to provide reimbursement under the program.

Added by Acts 2019, 86th Leg., R.S., Ch. 1157 (H.B. 3147), Sec. 2,

eff. September 1, 2019.